510(K) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01545
Telephone: 508-683-4359
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Contact: Ashley Pyle
Director Regulatory Affairs
Date Prepared: September 12, 2011

2. Device:

Trade Name: LeVeen SuperSlim Needle Electrode
Common Name: Electrode, Electrosurgical
Classification Name: Electrosurgical cutting and coagulation device and accessories
Regulation Number: 878.4400
Product Code: GEI
Classification: Class II

3. Predicate Device:

Boston Scientific Corporation's LeVeen Superslim Needle Electrode, K092009

4. Device Description:

The description of the proposed modified LeVeen Needle Electrode is the same as the predicate devices. The LeVeen SuperSlim Needle Electrode consists of a pre-shaped, multi-armed electrode array which is contained within a delivery cannula. The array is attached to a handle mechanism that deploys the array into targeted tissue. The device is connected to a generator so that RF energy passes from the array to a patient ground pad and heats the tissue surrounding the array.

5. Intended Use:

The LeVeen SuperSlim Needle Electrode is intended to be used in conjunction with a radiofrequency (RF) generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions.

6. Technological Characteristics:

The proposed Leveen Superslim Needle Electrode device will have PEEK insulation. The currently cleared Leveen Superslim Needle Electrode insulation material is FEP (K092009).

The proposed Leveen Superslim Needle Electrode device has a modified handle and cannula design as compared to the currently cleared Leveen Superslim Needle Electrode (K092009).

7. Performance Data:

Bench Testing has been performed on the proposed Leveen Superslim Needle Electrode device with PEEK insulation, which demonstrates that the PEEK insulation met the required specifications for the completed design verification, electrical tests and biocompatibility tests.

Bench Testing has been performed on the proposed Leveen Superslim Needle Electrode device with modified handle and cannula design, which demonstrates that the handle and cannula re-design met the required specifications for the completed design verification tests.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Leveen Superslim Needle Electrode is substantially equivalent to the currently cleared Leveen Superslim Needle Electrode (K092009).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 15 2012

Boston Scientific Corporation
% Ms. Ashley Pyle
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K113090
Trade/Device Name: LeVeen SuperSlim Needle Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 02, 2012
Received: March 05, 2012

Dear Ms. Pyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5
INDICATIONS FOR USE STATEMENT

Indications for Use:

510(k) Number (if known): **To Be Determined** K113090

Device Name: **LeVeen SuperSlim Needle Electrode**

Indications For Use:

The LeVeen SupersSlim Needle Electrode is intended to be used in conjunction with a radiofrequency (RF) generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113090